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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/790,561 | 03/01/2004 | James F. Zucherman | 19433A-004000US | 9704 |
| 20350 7590 07/20/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | EXAMINER CUMBERLEDGE, JERRY L | |
| | | | ART UNIT 3733 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,561

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,8,24,25,30,31 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,8,24,25,30,31 and 33-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 7, 8, 24, 25, 30, 31 and 33-47 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 34, 41, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the first tether" in line 20. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 8, 24, 25, 30, 31 and 33-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Appleton

Appleton discloses an implant (Fig. 6, below) adapted to be inserted between adjacent first and second spinous processes comprising: a planar unitary body; a first end of the planar unitary body that defines a first saddle that is adapted to be in direct contact with the first spinous process; a second end of the planar unitary body that defines a second saddle that is adapted to be in direct contact with the second spinous process; a first tether/fastener (Fig 3, ref. 14) associated with the first saddle; a second tether/fastener (Fig. 3, ref. 14) (column 2, lines 57-61) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain the second spinous process relative to the second saddle and wherein the first saddle is defined between a first leg (Fig. 6, below) and a first side of the planar unitary body and the second saddle is defined between a second leg (Fig. 6, below) and a second side of the planar unitary body with the first tether associated with the first leg and the first side of the planar unitary body and the second tether associated with the second leg and the second side of the planar unitary body (Fig. 6, Fig. 3). The first tether is separate from the second tether (Fig. 6, Fig. 3). The unitary body is configured to distract the first and second spinous processes (Fig. 6). The first tether is securable through a first bore (Fig. 6, cylindrical bore through the first leg) in the first leg and the second tether (Fig. 6, cylindrical bore through the second leg) is securable through a second bore in the second leg. The first tether is securable through a first bore in the first leg and is securable to the first side of the body and the second tether is securable through a second bore in the second leg and is securable to the second side of the body (Fig. 6). The first fastener is adapted to surround the first

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spinous process (Fig. 3) and the second fastener is adapted to surround the second spinous process

Appleton discloses an interspinous process implant adapted to be inserted between a first and a second spinous process comprising: a planar unitary body (Fig. 6, below) having a first end defining a first saddle, and a second end defining a second saddle, where the first and second saddles are adapted to directly engage first and second spinous processes, respectively; a first fastener (Fig 3, ref. 14) secured to the first saddle, where the first fastener is adapted to surround the first spinous process; and a second fastener (Fig. 3, ref. 14) (column 2, lines 57-61) secured to the second saddle, where the second fastener is adapted to surround the second spinous process. At least one of the first or second fasteners is a tether (Fig. 3, ref. 14).

Appleton discloses, in an interspinous process implant, the improvement comprising a unitary central planar body (Fig. 6 below) with first and second saddles adapted to receive adjacent spinous processes, the interspinous process implant having at least one tether (Fig 3, ref. 14) secured to at least one saddle in order to retain the interspinous process implant between the interspinous processes. The unitary body is configured to distract the first and second spinous processes (Fig. 6).

Appleton discloses, in an interspinous process implant (Fig. 6, below), the improvement comprising a unitary planar body with first and second saddles adapted to receive adjacent spinous processes, the interspinous process implant having a first tether (Fig 3, ref. 14) secured relative to one saddle and a second tether (Fig 3, ref. 14) (column 2, lines 57-61) that is secured relative to the other saddle in order to retain the

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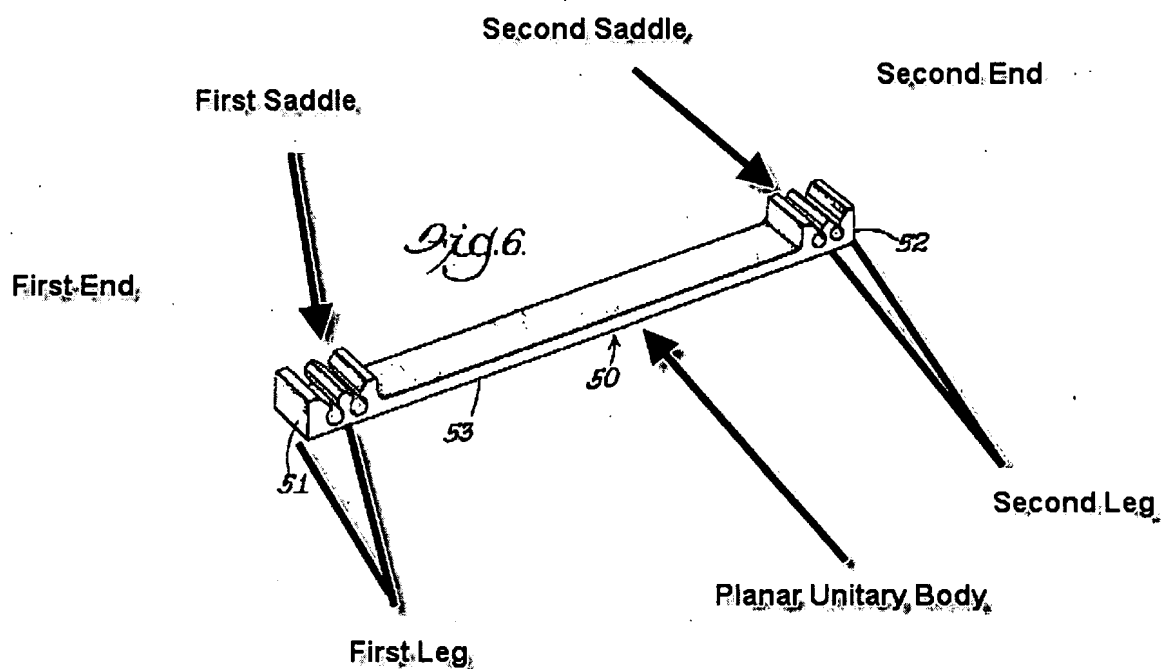
interspinous process implant between the interspinous processes. The implant is configured to distract the adjacent spinous processes (Fig. 6). The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body (Fig. 6, Fig. 3).

Appleton discloses an implant adapted to be inserted between adjacent first and second spinous processes comprising: a flat unitary body (Fig. 6, below); a first end of the flat unitary body that defines a first saddle; a second end of the planar unitary body that defines a second saddle; a first tether (Fig 3, ref. 14) associated with the first saddle; a second tether (Fig 3, ref. 14)(column 2, lines 57-61) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain the second spinous process relative to the second saddle wherein the first saddle is adapted to be in direct contact with the first spinous process and the second saddle is adapted to be in direct contact with the second spinous process; and wherein the first saddle is associated with a first leg (Fig. 6, below) and a first side of the flat unitary body and the second saddle is associated with a second leg (Fig. 6, below) and a second side of the flat unitary body. The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body.

Appleton discloses an implant (Fig. 6, below) adapted to be inserted between adjacent first and second spinous processes comprising: a planar body; a first end of the planar body that defines a first saddle; a second end of the planar body that defines a second saddle; a first tether (Fig 3, ref. 14) associated with the first saddle; a second

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tether (Fig 3, ref. 14)(column 2, lines 57-61) associated with the second saddle; the first tether adapted to retain the first spinous process relative to the first saddle; the second tether adapted to retain the second spinous process relative to the second saddle wherein the first saddle is adapted to be associated with the first spinous process and the second saddle is adapted to be associated with the second spinous process; and wherein the first saddle is associated with a first leg and a first side of the planar body and the second saddle is associated with a second leg and a second side of the planar body with the first tether associated with the first leg and the first side of the planar body and the second tether associated with the second leg and the second side of the planar body (Fig. 6, Fig. 3). The first tether is securable to the first leg and to the first side of the body and the second tether is securable to the second leg and to the second side of the body (Fig. 3 and Fig. 6).



With regard to statements of intended use and other functional statements (e.g. ...adapted to be inserted between adjacent first and second spinous processes..., ...the unitary body is configured to distract the first and second spinous processes...), they do not impose any structural limitations on the claims distinguishable over the device of Appleton, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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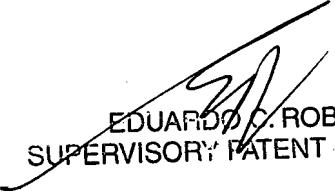
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER